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Special 510(k) Device Modification - Summary

This Special 510(k) Device Modification is to provide substantial equivalence for the Advanced Medical Solutions Limited's Silver Alginate II Dressing, which is substantially equivalent to currently marketed devices intended for wound care. This product is already legally marketed as Silver Alginate II dressing (unmodified device) and was previously cleared under 510(k) # **K041316, K063173** and **K070581**. All submissions were made by Advanced Medical Solutions Limited.

Submitted by:-

Advanced Medical Solutions Limited
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United Kingdom

Contact:-

Mrs. Claire Ryan
Regulatory Affairs Manager
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Date prepared:- 20th February 2009

Common Name:- Silver Alginate II Dressing

Trade Names:- To be confirmed

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Product Code:- FRO

Legally marketed device(s) for which substantial equivalence is claimed:-
Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, manufactured by Advanced Medical Solutions.

Device Description:-
Silver Alginate II Dressing is a sterile, non woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (Silver Sodium Hydrogen Zirconium Phosphate), which releases silver ions in the presence of wound fluid. As wound fluid is absorbed the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to fourteen (14) days, based on *in-vitro* testing. Odour reduction results from the antibacterial effect in the dressing.

Silver Alginate II Dressing is an effective barrier to bacterial penetration.

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Silver Alginate II Dressing protects the wound and aids autolytic debridement therefore facilitating wound healing.

The Silver Alginate II Dressing is available various sizes; 5cm x 5cm (2" x 2"), 10cm x 10cm (4" x 4"), 10cm x 12cm (4" x 4.75"), 15cm x 15cm (6" x 6"), 10cm x 20cm (4" x 8"), 20cm x 30cm (8" x 12") and 2.7cm x 30cm (1" x 12"). The dressings are packaged in foil pouches.

Indications for use:
Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, such as pressures ulcers, diabetic ulcers, leg ulcers, post-operative wounds, trauma wounds (dermal lesions, trauma injuries or incisions), graft and donor sites, post-operative surgical wounds, 1st and 2nd degree burns.

Silver Alginate II Dressing is indicated for external use only.

Manufacturing:-
Silver Alginate II Dressing will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Advanced Medical Solutions Ltd Silver Alginate II Dressing meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

Testing:-
Performance data for the Silver Alginate II Dressing has been established using antimicrobial and bench testing. The biocompatibility of Advanced Medical Solutions Limited Silver Alginate II Dressing has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with ISO 11137standards.

The biocompatibility testing, *in-vitro* performance testing and microbiological assessment for the Silver Alginate II Dressing has demonstrated that the device is safe and effective for the indications of use.

Statement of Substantial Equivalence:-
The indication for use, performance testing and antimicrobial activity for the Silver Alginate II Dressing is substantially equivalent to the predicate devices; Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, manufactured by Advanced Medical Solutions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Solutions Limited
% Ms. Claire Ryan
Regulatory Affairs Manager
Road Three, Winsford Industrial Estate
Winsford, Cheshire
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United Kingdom

FEB 2 6 2009

Re: K090453
Trade/Device Name: Silver Alginate II Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2009
Received: February 23, 2009

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090453

Device Name: **Silver Alginate II Dressing**

Indications for Use:

Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, such as:

- Post-operative wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- Leg ulcers
- Pressure ulcers
- Diabetic ulcers
- Graft and donor sites
- Post-operative surgical wounds
- 1st and 2nd degree burns
- Partial and full thickness wounds

Silver Alginate II Dressing is indicated for external use only

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone 2/26/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090453